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Market Access, the New Approach and Private Law

Barend VAN LEEUWEN*

Abstract: In *James Elliott* and *Schmitt*, the ECJ refused to extend the scope of application of European standards adopted under the New Approach to private law disputes. This article argues that the ECJ's judgments were based on a static interpretation of the concept of market access, which is inconsistent with how the concept of market access has been developed in free movement of goods cases under Article 34 TFEU. It argues for a more consistent and dynamic interpretation of market access. Such an approach would bring private liability cases like *James Elliott* and *Schmitt* within the scope of application of EU law. As a result, the conditions and requirements for liability in private law could be reviewed by the ECJ. If the ECJ is not willing to extend the scope of application of the New Approach in this way, the EU legislature should include rules on private liability in the directives adopted under the New Approach.

Résumé: Dans les affaires *James Elliott* and *Schmitt*, la CJUE a refusé d'étendre le champ d'application des standards européens adoptés dans le cadre de la Nouvelle Approche des contentieux de droit privé. Cet article suggère que les arrêts de la CJUE se basent sur une interprétation statique du concept d'accès au marché, une interprétation qui ne correspond pas au concept développé dans les arrêts relatifs à la libre circulation des biens suivant l'article 34 TFUE. Cet article défend une interprétation cohérente et dynamique de l'accès au marché. Une telle approche placerait les cas de contentieux privé comme *Elliott* and *Schmitt* dans le champ d'application du droit européen. Par conséquent, les conditions et exigences de responsabilité en droit privé pourraient être examinées par la CJUE. Si cette dernière n'est pas disposée à étendre le champ d'application de la Nouvelle Approche de cette manière, le législateur européen devrait inclure des règles sur la responsabilité privée dans les directives adoptées dans le cadre de la Nouvelle Approche.

Zusammenfassung: In *James Elliott* und *Schmitt* lehnte es der EuGH ab den Anwendungsbereich europäischer Normen, die unter dem "Neuen Konzept" erlassen wurden auf private Rechtsstreitigkeiten auszuweiten. Dieser Beitrag argumentiert, dass diese EuGH-Rechtsprechung, die auf einer statischen Auslegung des Konzepts des Marktzugangs beruhte, nicht im Einklang mit der Entwicklung des Konzepts des Marktzugangs in der Rechtsprechung zur freien Warenfreiheit nach Artikel 34 AEUV steht. Es wird für eine einheitlichere und dynamischere Auslegung des Konzepts des Marktzugangs plädiert. Ein solcher Ansatz würde privatrechtliche Haftungsfälle wie *Elliott* und *Schmitt* dem Anwendungsbereich des EU-Rechts unterstellen. Somit könnten die Voraussetzungen und Bedingungen für die Haftung vom EuGH

* Assistant Professor in EU Law at Durham University, United Kingdom. I am grateful to Mislav Mataija, Paul Verbruggen and Steve Weatherill for the comments and discussions. The final version of this article was submitted on 23 February 2019. Email: barend.j.van-leeuwen@durham.ac.uk.

überprüft werden. Falls der EuGH nicht bereit ist, den Anwendungsbereich des “Neuen Konzepts” auf diese Weise auszuweiten, sollte der EU-Gesetzgeber Regeln für die privatrechtliche Haftung in den Richtlinien zum “Neuen Konzept” aufnehmen.

1. Introduction

1. In two recent judgments, *James Elliott*¹ and *Schmitt*,² the Court of Justice of the EU (‘the Court’) had to consider the impact of the New Approach, the EU’s regulatory framework to improve the free movement of goods, on private law claims arising after products had been placed on the market. The New Approach has given an important role to the European standardization organizations, which adopt the standards with which goods have to comply before they can be placed on the market. In *James Elliott*, the Court held that it was competent to interpret these harmonized standards in a preliminary reference brought under Article 267 TFEU. The judgment was seen as revolutionary, because the Court was prepared to interpret standards which have been developed by private standardization organizations.³ *Schmitt* was considerably less revolutionary, since the Court held that EU law does not require that certification bodies, which verify if manufacturers comply with the relevant European standards, can be held liable to end-users of products covered by the New Approach if they have acted negligently in the certification procedure.⁴ Nevertheless, the Court recognized that the aim of the involvement of certification bodies is to protect the health of end-users of products.

2. This article will argue that, from the perspective of private law, the judgment in *James Elliott* was not revolutionary at all. The Court was unwilling to extend the scope of application of the New Approach to private law disputes which arise after products have been placed on the market. Therefore, it is not necessary for national courts to make a preliminary reference on the interpretation of European standards in private law disputes. After all, the European

1 ECJ 27 October 2016, C-613/14, *James Elliott Construction Ltd v Irish Asphalt Ltd*, ECLI:EU:C:2016:821.

2 ECJ 16 February 2017, C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, ECLI:EU:C:2017:128

3 See A. VOLPATO, ‘Harmonised Standards before the ECJ’, 54. *CML Rev* 2017, p 591 and A. VAN WAEYENBERGE & D. RESTREPO AMARILES, ‘James Elliott Construction: a New(ish) Approach to Judicial Review of Standardisation’, 42. *EL Rev* 2017, p 882.

4 See P. VERBRUGGEN & B. VAN LEEUWEN, ‘The Liability of Notified Bodies under the EU’s New Approach: The Implications of the PIP Breast Implants Case’, 43. *EL Rev* 2018, p 394 and A. WALLERMAN, ‘Pie in the Sky when you Die? Civil Liability of Notified Bodies under the Medical Devices Directive’, 55. *CML Rev* 2018, p 265. See also GLINSKI & ROTT in this issue (with further references).

standard does not have a direct impact on the outcome of the dispute. A similarly restrictive interpretation of the impact of the New Approach on private law can be seen in *Schmitt*. It will be argued that both judgments are based on a static concept of market access, which is only concerned with the initial placing on the market of products. This concept of market access under the New Approach is inconsistent with how market access has been developed by the Court under Article 34 TFEU. Because the New Approach and Article 34 TFEU both aim to facilitate free movement of goods, a more consistent interpretation of market access should be adopted. Moreover, the effective application of the New Approach requires that European standards have an impact on private law rules. A direct link between the New Approach and private law will help to improve free movement of goods in the internal market.

3. The argument in this article will be developed in three steps. First, it will be shown that both *James Elliott* and *Schmitt* are based on a static concept of market access (2). Second, this approach to market access is inconsistent with the Court's case law under Article 34 (3). Third, a more integrated approach to market access under the New Approach and Article 34 TFEU is necessary. Such an approach would require that the scope of application of the New Approach is extended to private law disputes (4). If the Court remains unwilling to make this link, the European legislature should be encouraged to include rules on private law liability in the legislation adopted under the New Approach.

2. Market Access Under the New Approach

2.1. *James Elliott*

4. *James Elliott* was a sale of goods case. The Irish building company James Elliott concluded a contract with Irish Asphalt for the sale of Clause 804 aggregate – a particular kind of concrete used in construction – which was to be used in building a school in Dublin. After the completion of the building works, it was discovered that the aggregate contained pyrite, which caused damage to the concrete floors and ceilings. As a result, James Elliott had to carry out a significant amount of remedial work. The company subsequently brought a case against Irish Asphalt for breach of contract. Under the Irish Sale of Goods and Supply of Services Act 1980, where the seller sells goods in the course of a business, there is an implied condition that the goods supplied under the contract are of merchantable quality and are reasonably fit for purpose.⁵ The Irish High Court held that the European standard for construction products, adopted under the New Approach, had to be used in deciding whether these terms had been complied with. It found that there

5 S. 10 of the Sale of Goods and Supply of Services Act 1980.

had been a breach of contract because the aggregate did not satisfy the requirements of the European standard. The breach of the European standard was used in support of the finding that there had been a breach of contract. It was in this contractual context that, on appeal, the Irish Supreme Court made a preliminary reference to the Court.

5. In understanding *James Elliott*, it should be recalled that, on a first impression, the New Approach does not appear to be concerned with the harmonization of national contract law. The EU developed the New Approach as a regulatory framework to improve the free movement of goods in the internal market.⁶ The EU adopts general product safety directives, which are supplemented with European standards that ‘fill in’ the technical specifications which products have to comply with. These harmonized European standards are adopted by one of the European standardization organizations. If manufacturers comply with the relevant European standard, it is presumed that they also satisfy the ‘essential requirements’ of the directive. As such, establishing compliance with the European standard has become the main mechanism for manufacturers to prove that they comply with the European legislation. If they are able to show this, they can lawfully place their products on the market.

6. In *James Elliott*, the relevant directive was Directive 89/106.⁷ Article 2(1) confirms that construction products can only be placed on the market if they are fit for their intended use, which means that they satisfy the essential requirements under the Directive. It is not difficult to make a link between the concept of ‘fitness for use’ in Article 2(1) of Directive 89/106 and the implied condition of ‘fitness for purpose’ and ‘merchantable quality’ in the Irish Sale of Goods Act 1980. This is precisely what the Irish courts had done in their interpretation of the Sale of Goods and Supply of Services Act 1980. Nevertheless, the Court of Justice declined to impose this link as a matter of EU law. The concept of fitness for purpose under Directive 89/106 was kept separate from the concept of fitness for purpose under the Irish Sale of Goods Act. EU law did not require that the European standard was used to determine whether there had been a breach of contract.

7. The Court’s judgment made it clear that, from the perspective of EU law, compliance with the European harmonized standard is only required for manufacturers to be able to place their products on the market. In other words, Irish Asphalt had to show that the aggregate complied with the relevant European

6 For a more detailed explanation of the New Approach, see H. SCHEPEL, *The Constitution of Private Governance* (Oxford: Hart 2005) and B. VAN LEEUWEN, *European Standardisation of Services and its Impact on Private Law* (Oxford: Hart 2017).

7 Directive 89/109 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products.

standard at the moment when it was placed on the Irish market. The role that the European standard played in a contractual dispute which arose *after* the product had been placed on the market was not regulated by the New Approach. The Court held that the European standard did not determine the method for establishing the conformity of the product with the contractual specifications.⁸ Similarly, it held that national courts were under no obligation imposed by EU law to apply the presumption of fitness under the Directive to the contractual dispute.⁹

8. As a result, from a private law perspective, the revolutionary impact of the judgment is significantly restricted. The Court held that it is competent under Article 267 TFEU to provide an interpretation of harmonized European standards adopted under the New Approach. At the same time, it held that the interpretation or application of a European standard in a contractual dispute is not a matter of EU law. Therefore, it is not necessary for national courts to ask the Court questions about the interpretation of European standards in private law cases. This makes it significantly less likely that national courts will make references on the interpretation of European standards in private law disputes. The only type of cases in which preliminary references might be necessary are administrative law cases – for example, where the public authorities in a Member State are refusing to allow a particular product to be placed on the market because they claim that the product does not comply with the relevant European standard. This is precisely what happened in the recent case of *Anstar*,¹⁰ in which the Finnish authorities refused to allow Anstar’s construction products to be placed on the Finnish market. It explains why the judgment in *James Elliott* has been regarded as revolutionary from an administrative law perspective.¹¹ However, from the perspective of private law, the judgment in *James Elliott* cannot be regarded as a revolution. This does not mean that European standards play no role in private law. National courts regularly rely on European standards to determine the appropriate contractual standard of care or the required standard of care in tort cases based on fault.¹² However, *James Elliott* makes it clear that the application of European standards to contractual disputes is not imposed – or even controlled – by EU law.

8 C-613/14, *James Elliott* (n 1), para. 53.

9 *Ibid.*, at para. 61.

10 ECJ 14 December 2017, C-630/16, *Anstar Oy*, ECLI:EU:C:2017:971.

11 See M. ELIANTONIO, ‘Judicial Control of the EU Harmonized Standards: Entering a Black Hole?’, 44. *LIEI (Legal issues of Economic Integration)* 2017, p 395.

12 See H. SCHEPEL, *Constitution of Private Governance*, Ch. 4. See also F. CAFAGGI, ‘Private Regulation in European Private Law’, in A. Hartkamp et al. (eds.), *Towards a European Civil Code* (Alphen aan de Rijn: Kluwer 2011), pp 91-126.

2.2. *Schmitt*

8. A similarly restrictive interpretation of the impact of the New Approach on private law can be seen in *Schmitt*, which was a tort law case. Elisabeth Schmitt was a German woman who had received breast implants which had possibly been manufactured by the French PIP factory. For a significant period of time, PIP had used substandard industrial silicone gel in producing the breast implants. Breast implants are covered by the New Approach – more precisely, by the Medical Devices Directive.¹³ PIP's fraud meant that their implants did not actually comply with the relevant European standard. However, the fraud was never discovered by the certification body TÜV Rheinland ('TÜV'), which was responsible for the conformity assessment procedure to verify that the breast implants complied with the European standard. As a result, PIP was able to continue to place its products on the market. Because the factory had gone bankrupt, Ms Schmitt decided to bring a case against the certification body which had been responsible for the conformity assessment procedure. She brought a damages claim against TÜV and submitted that it had been negligent in performing the conformity assessment procedure under the New Approach.

9. The main questions for the German court were whether TÜV owed a duty of care to the recipients of breast implants, like Ms Schmitt, and whether it had breached that duty of care. Under German law, TÜV could be found to owe a duty of care to Ms Schmitt if the conformity assessment procedure was intended to protect end-users like Ms Schmitt.¹⁴ The lower German courts held that TÜV had not acted to protect end-users, because the focus of its certification activities was on facilitating the manufacturer in placing its products on the market.¹⁵ Therefore, TÜV did not owe a duty of care to Ms Schmitt in tort. Moreover, they held that TÜV had not acted negligently in performing the conformity assessment procedure. The German Supreme Court decided to make a preliminary reference and asked whether certification bodies under the New Approach act with the aim to protect end-users, whether the Medical Devices Directive required that notified bodies could be held liable to end-users, and whether TÜV had breached its obligations under the Medical Devices Directive.

10. The Court of Justice held that, in addition to facilitating free movement of goods in the internal market, the aim of the involvement of certification bodies in the New Approach is also to protect the end-users of products.¹⁶ However, the New

13 Directive 93/42 concerning medical devices.

14 For more background, see B. VAN LEEUWEN, 'PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies', 5. *EJRR* 2014, p 338.

15 Landgericht Frankenthal (Pfalz) 14 March 2013, 6 O 304/12, ECLI:DE:LGFRAPF:2013:0314.6O304.12.0A, and Oberlandesgericht Zweibrücken 30 January 2014, 4 U 66/13, ECLI:DE:POLGZWE:2014:0130.4U66.13.0A.

16 C-219/15, *Schmitt* (n 2), para. 53.

Approach does not require that certification bodies can be held liable in tort. In other words, liability in tort law is not imposed as a matter of EU law. For that reason, the conditions under which certification bodies can be held liable in negligence under national law are not regulated by EU law.¹⁷ Nevertheless, they have to comply with the principles of equivalence and effectiveness.¹⁸ Finally, the Court held that notified bodies were not obliged to carry out unannounced inspections, to examine devices or to examine the manufacturer's business records.¹⁹ The Court knew that its finding that the aim of the involvement of certification bodies in the New Approach was to protect end-users was sufficient for the German Supreme Court to establish a duty of care under German law. It also knew that it was unlikely that the German court would found a breach of TÜV's duty of care in light of the Court's judgment.²⁰

11. The Court's conclusion that the Medical Devices Directive did not require that certification bodies could be held liable in tort was to a significant extent based on its judgment in *Paul*.²¹ In that case, the Court held that a directive on banking supervision did not require that public supervisory agencies in the banking sector could be held liable to individual victims for breaches of the directive. It relied on two justifications in support of this conclusion: first of all, the directive itself did not provide for the liability of public supervisory agencies in case of non-compliance; secondly, State liability was not necessary to guarantee the effective application of the directive.²² In *Schmitt*, the Court only focussed on the first justification. The Medical Devices Directive does not expressly impose liability on certification bodies. The more fundamental question of whether the effectiveness of the New Approach required that certification bodies could be held liable to end-users in tort was not addressed by the Court. Its conclusion was that the liability of certification bodies remained a matter of national law.

12. In *Schmitt*, we can observe a similar unwillingness on the part of the Court to extend the impact of the New Approach to private law. Even though certification bodies have a monitoring role *after* a product has been placed on the market, since they have to ensure that manufacturers still comply with the European standard,

17 *Ibid.*, at para. 59.

18 For an analysis of why the Court held that the principles of equivalence and effectiveness were applicable to this case, see P. VERBRUGGEN & B. VAN LEEUWEN, 43. *EL Rev* 2018, pp 401–402, and A. WALLERMAN, 55. *CML Rev* 2018, p 275.

19 *Ibid.*, at para. 48.

20 Indeed, the Bundesgerichtshof (German Supreme Court) rejected Ms Schmitt's claim on the basis that TÜV had not breached its obligations under the New Approach: Bundesgerichtshof, 22 June 2017, VII ZR 36/14, ECLI:DE:BGH:2017:220617UVIIZR36.14.0.

21 ECJ 12 October 2004, C-222/02, *Peter Paul and others v Bundesrepublik Deutschland*, ECLI:EU:C:2004:606.

22 *Ibid.*, at paras 42–47.

their activities are limited to guaranteeing that manufacturers continue to have the right to place their product on the market. The potential liability of certification bodies in the New Approach remains a question of national law. More fundamentally, the Court was not willing to analyse to what extent the effective application of the New Approach requires that certification bodies can be held liable in tort as a matter of EU law.

2.3. *A Static Concept of Market Access*

13. A number of parallels between *James Elliott* and *Schmitt* can be identified. In both cases, the Court of Justice adopted a narrow perspective on the scope of the New Approach. More precisely, the impact of the New Approach on private law was restricted. The Court was unwilling to extend the impact of the New Approach beyond the question of whether products could be lawfully placed on the market. The application of European standards in contract law and the liability of certification bodies in tort law remain regulated by national law with little or no EU law control. This approach to the impact of the New Approach on private law is based on a static vision of market access in the internal market. Furthermore, it is based on a restrictive vision of the role that private law plays in facilitating market access. It will be argued below that this static concept of market access under the New Approach is inconsistent with how the Court of Justice has developed the concept of market access in its case law under Article 34 TFEU. Moreover, it will be argued that it is inconsistent with the role that the EU has given to private law in strengthening the internal market and in facilitating free movement. This theme will be returned to in the final section. First, it is necessary to analyse in more detail how and why the judgments in *James Elliott* and *Schmitt* are based on a static concept of market access.

14. In both judgments, the Court of Justice construed the concept of market access under the New Approach as restricted to the placing on the market of products. The ‘reach’ of the New Approach does not extend beyond this initial stage. Essentially, this means that the New Approach is seen as an administrative law project. It regulates the relationship between manufacturers of products and the public authorities in the Member State where they want to place their product on the market. These public authorities cannot obstruct the placing on the market of products which comply with the essential requirements of the relevant directive. If products comply with the European standard, it is presumed that they also comply with the essential requirements of the directive. However, once the products have been placed on the market, the New Approach no longer regulates or assists the manufacturer. In particular, this means that the role that the European standard plays in private law is not regulated by EU law. There is no direct link between the New Approach and private law.

15. This is a static interpretation of the role of the New Approach and of the concept of market access, since it presumes that national rules which regulate the use of a product after it has been placed on the market do not have a direct impact on market access. In *James Elliott*, the relevant directive was Directive 89/106. The first paragraph of Article 6(1) of the same Directive provides that ‘Member States shall not impede the free movement, placing on the market or use in their territory of products which satisfy the provisions of this directive’. As such, it is clear that the use of products in the territory of the Member States cannot be obstructed under the New Approach. The second paragraph of Article 6(1) goes on to say that ‘Member States shall ensure that the use of such products, for the purpose of which they are intended, shall not be impeded by rules or conditions imposed by public bodies or private bodies acting as a public undertaking or acting as a public body on the basis of a monopoly position’. This last addition emphasizes the potential role of competition law in facilitating market access, while the first paragraph highlights the role of the free movement provisions.²³ Because of the static view of market access under the New Approach, national rules which impede the use of products after they have been placed on the market should be assessed under the free movement provisions or competition law. In other words, the scope of positive integration through the New Approach is limited to the initial market access stage.

16. As a result, in *James Elliott*, the concept of ‘fitness for use’ under Article 2(1) of Directive 89/106 did not have a direct impact on the concept of ‘fitness for purpose’ under the Sale of Goods and Supply of Services Act 1980. From the perspective of manufacturers, this makes little business sense. They have to ensure that their products comply with the European standard before they can be placed on the market, but this standard does not have to be used to assess their fitness for use in private law disputes which arise after the products have been placed on the market. However, without an express agreement between the seller and buyer, it is difficult to see why a product should suddenly be expected to comply with a different standard in private law. If the product was fit for use when it was placed on the market, why would it not be fit for purpose when it was actually being used? Moreover, in cases like *James Elliott*, where the aggregate was supplied to be used in construction work, the distinction between the *placing* on the market of the aggregate and its *use* appears artificial and difficult to demarcate in practice. If Irish law required the aggregate in *James Elliott* to comply with additional and more stringent standards than those contained in the European standard in a contractual dispute, these requirements could be regarded as an obstacle to free movement under Article 34 TFEU. This would have a negative impact on the access

23 For an analysis of the interaction between the New Approach and competition law, see B. LUNDQVIST, *Standardization under EU Competition Rules and US Antitrust Rules* (Cheltenham: Edward Elgar 2014).

to the market of products which complied with the European standard. As a result, the effectiveness of the New Approach would be compromised. Similarly, in *Schmitt*, the refusal of the Court to impose the possibility of liability of certification bodies under the New Approach could have an impact on the willingness of consumers to buy products covered by the New Approach. If consumers cannot hold certification bodies liable for having acted negligently in the certification procedure, this could mean that they are less willing to buy a product. Consumer confidence plays an important role in the way in which market access has been interpreted under Article 34 TFEU.

17. Overall, it can be concluded that the scope of the New Approach has been restricted to a static interpretation of market access. As a result, there is no EU-law control beyond the initial market access stage. This might not be sufficient to guarantee the effective application of the New Approach. Moreover, it is not consistent with the dynamic approach to market access which the Court has developed in its case law under Article 34 TFEU. If this concept of market access is applied to private law cases for products covered by the New Approach, it would increase the effectiveness of the EU's regulatory framework. It would require a more flexible and more integrated approach to positive integration through the New Approach and negative integration under Article 34 TFEU. Before this integrated approach will be analysed in more detail in the last section, we will first look at how the Court has interpreted the concept of market access in its case law under Article 34 TFEU.

3. Market Access Under Article 34 TFEU

3.1. *Keck*

18. There is a close relationship between the creation of the New Approach and the Court's case law under Article 34 TFEU. The judgment in *Cassis de Dijon*,²⁴ in which the Court introduced the principle of mutual recognition and the concept of mandatory requirements, provided an important impetus to the EU to develop the New Approach. National product standards which required products to comply with an additional or different set of standards from the Member State where they had been produced were held to be measures having equivalent effect under Article 34 TFEU. If the EU wanted to deal effectively and efficiently with the variety of national product standards that existed in the Member States, it had to come up with a new regulatory approach to remove obstacles to free movement.²⁵ Negative integration through Article 34 TFEU alone was not sufficiently effective. Harmonization of laws on the basis of Article 114 TFEU was a long and

24 ECJ 20 February 1979, C-120/78, *Rewe-Zentral AG*, ECLI:EU:C:1979:42.

25 See H. SCHEPEL, *Constitution of Private Governance*, pp 63–69.

complicated political process, which was not sufficiently efficient to deal with rapid technological developments in the field of goods. For that reason, the EU decided to outsource the technical aspects of the standard-setting for products to European standardization. Therefore, there is a close link between the New Approach and Article 34 TFEU. Both regulatory tools play an important and complementary role in improving the free movement of goods in the internal market. The aim of this section is to show that, despite the parallel aims of the New Approach and Article 34 TFEU, the concept of market access under Article 34 TFEU has been developed in a way which is different from the Court's approach in *James Elliott* and *Schmitt*.

19. In its early case law under Article 34 TFEU, the focus of the Court was on product requirements. Because of the broad definition of a measure having equivalent effect established by the Court in *Dassonville*,²⁶ traders increasingly tried to rely on Article 34 TFEU to challenge a variety of national rules that they regarded as obstacles to free movement. This line of cases, with the Sunday Trading Saga as the main example,²⁷ revealed the increasing tension between the interests of businesses, which were trying to use Article 34 TFEU as a tool to challenge national rules that were restrictive of trade, and the interests of the Member States, which wanted to maintain a certain degree of regulatory autonomy. The Member States were worried about constantly having to justify national legislation under Article 34 TFEU – even if the legislation had little to do with cross-border trade. In *Keck*, the Court of Justice finally attempted to deal with this tension by making a fundamental distinction between national rules that regulate the physical characteristics of a product and national rules that regulate the circumstances under which a product can be sold.²⁸ The former category of rules ('product requirements') is caught by Article 34 TFEU, while the latter category ('selling arrangements') falls outside the scope of Article 34 TFEU.²⁹ The aim of the judgment was to redefine the boundaries of the scope of Article 34 TFEU and to protect the regulatory autonomy of the Member States.

20. The concept of market access constituted one of the key foundations of the Court's judgment in *Keck*. On a first impression, it could be argued that *Keck* is consistent with the restrictive approach to market access adopted by the Court in *James Elliott* and *Schmitt*. After all, the focus of the judgment is on the distinction between national rules that directly affect the access of products to the market – such as product requirements – and rules that are about the circumstances under which products are sold. This seems to be based on a similar static interpretation of the concept of market access, since rules that regulate the sale of a product fall outside

26 ECJ 11 July 1974, C-8/74, *Dassonville*, ECLI:EU:C:1974:82.

27 ECJ 23 November 1989, C-145/88, *Torfaen Borough Council*, ECLI:EU:C:1989:584.

28 ECJ 24 November 1993, C-267-268/91, *Keck and Mithouard*, ECLI:EU:E:1993:905.

29 *Ibid.*, at para. 15.

the scope of Article 34 TFEU. However, the Court also recognized in *Keck* that there might be certain circumstances in which selling arrangements can still constitute a restriction of Article 34 TFEU. Therefore, the Court developed the so-called *Keck* proviso: selling arrangements only fall outside the scope of Article 34 TFEU if they apply to all relevant traders operating within the national territory and so long as they do not discriminate in law or in fact against products from other Member States.³⁰ The justification for this proviso was that national rules which comply with both conditions do not prevent or impede access to the market.³¹ As a result, it can be seen that the Court relied on the concept of market access in redefining the scope of application of Article 34 TFEU. The Court recognized that selling arrangements which discriminated against products from other Member States could have a negative impact on market access. This reflects a more dynamic definition of market access, which is not only concerned with the initial placing of products on the market, but also with rules which govern the conditions under which a product can be sold.

21. The way in which the Court has applied the *Keck* proviso in subsequent cases shows that market access has in fact become the key criterion in determining whether a selling arrangement falls outside the scope of Article 34 TFEU. Selling arrangements that prevent or hinder market access were found to be indirectly discriminatory and had to be justified and proportionate. The main examples of this type of rules are national rules on advertising. In *De Agostini*,³² the Court held that a national rule which restricted the ability of manufacturers to advertise their products could constitute a restriction on free movement. As a result, even though *Keck* initially seemed to be consistent with a more static approach to market access, the *Keck* proviso has subsequently been interpreted in such a way that it is possible to take national rules which govern the circumstances under which a product is sold into account in deciding whether or not there is a restriction on free movement. This has extended the reach of Article 34 TFEU beyond the initial market access stage. Therefore, the concept of market access under Article 34 TFEU seems broader than the Court's concept under the New Approach. However, *Keck* and the early post-*Keck* case law did not focus on rules which regulated the use of products. For a long time, it was unclear whether national rules on use could constitute restrictions on free movement.

3.2. *Commission v Italy (Trailers)*

22. The Court had an opportunity to consider national rules on use in *Commission v Italy (Trailers)*.³³ This case was about Italian rules which prohibited motorcycles from

30 *Ibid.*, at para. 16.

31 *Ibid.*, at para. 17.

32 ECJ 9 July 1997, C-34/95, *De Agostini*, ECLI:EU:C:1997:344.

33 ECJ 10 February 2009, C-110/05, *Commission v Italy*, ECLI:EU:C:2009:66.

towing a trailer. These rules clearly constituted a restriction on the use of trailers in Italy – more precisely, of those trailers which were specifically designed to be towed by motorcycles. The initial question for the Court was how such rules should be classified under Article 34 TFEU. The Commission argued that national rules which have a negative impact on the use of products should be assessed under the *Dassonville* test, while national rules which completely prohibited the use of a product should always be regarded as a measure having equivalent effect under Article 34 TFEU.³⁴ Some of the Member States argued that rules on use should be assessed as selling arrangements, because these rules do not affect the physical characteristics of a product.³⁵ Therefore, if they complied with the *Keck* proviso, these rules would fall outside the scope of Article 34 TFEU. This approach was also adopted by Advocate General (‘AG’) Kokott in the parallel case of *Mickelsson and Roos*,³⁶ which was about a Swedish ban on the use of jet skis on Swedish waters. She proposed to classify rules on use as selling arrangements and to assess them under the *Keck* test. At the same time, she found that national rules that completely restricted or banned the use of a product were likely to have a negative impact on market access and, consequently, did not satisfy the second *Keck* proviso. Therefore, the national rule constituted a measure having equivalent effect.

23. The Court did not follow the route suggested by AG Kokott in either *Commission v Italy* or *Mickelsson and Roos*. It developed a separate and self-standing test for rules that prevent or restrict the use of products. This rule is additional to the *Dassonville* test and the *Keck* proviso for selling arrangements and applies specifically to national rules on use.³⁷ The Court focussed on the impact of use restrictions on the behaviour of consumers. Because they make consumers less likely to buy a product, use restrictions have a negative impact on the access of the product to the Member State. According to the Court, ‘[c]onsumers, knowing that they are not permitted to use their motorcycles with a trailer specially designed for it, have practically no interest in buying such a trailer’.³⁸ As a result, the Italian legislation ‘prevents a demand from existing in the market at issue for such trailers and therefore hinders their importation’.³⁹ In *Mickelsson and Roos*, the Court formulated the test more precisely: rules on use that prevent or greatly restrict the use of a product for the specific purpose for which it is intended constitute measures having equivalent effect under Article 34 TFEU.⁴⁰ As a consequence, such national rules have to be justified and proportionate.

34 *Ibid.*, at para. 18.

35 *Ibid.*, at para. 22.

36 Opinion of AG Kokott, ECJ 14 December 2006, C-142/05, *Mickelsson and Roos*, ECLI:EU:C:2006:782.

37 For an analysis of the interaction between the different tests, see R. SCHÜTZE, ‘Of Types and Tests: Towards a Unitary Doctrinal Framework for Article 34 TFEU?’, 41. *EL Rev* 2016, p 826.

38 C-110/05, *Commission v Italy*, para. 57.

39 *Ibid.*

40 ECJ 4 June 2009, C-142/05, *Mickelsson and Roos*, ECLI:EU:C:2009:336, para.28.

3.3. *A Dynamic Concept of Market Access*

24. In *Commission v Italy (Trailers)* and *Mickelsson and Roos*, the Court adopted a broad definition of market access. The Court extended the scope of application of Article 34 TFEU to national rules on use. In doing so, it explicitly recognized that rules that govern the use of products may have an impact on market access and can create obstacles to free movement. A direct link was made between market access and national rules on the use of products. In *James Elliott*, the Court was unwilling to make this link for the New Approach. As a result, the scope of the New Approach does not extend to national legislation that governed the use of a product after it has been placed on the market. After *Commission v Italy (Trailers)* and *Mickelsson and Roos*, it is clear that the impact of the Irish legislation on implied conditions in sale of goods contracts could be reviewed under Article 34 TFEU – for example, if Irish law imposed different or additional standards on foreign products. In *Alsthom Atlantique*, the Court held that national contract law rules which applied without distinction and which did not have the effect of restricting intra-Community trade did not constitute a measure having equivalent effect under Article 34 TFEU.⁴¹ However, this does not exclude the possibility that national rules on the use of products could discriminate against foreign products or could restrict market access. The effectiveness of the New Approach would still be improved if EU law retained control over national rules on use. Therefore, it will be argued below that the scope of application of the New Approach should be extended, so that the Irish rules on fitness for purpose would be regulated by the standards of the New Approach rather than Article 34 TFEU. Before we will analyse the required ‘intensity’ of the EU-law control in the next section, the Court’s justifications for a dynamic interpretation of market access will be analysed.

25. In its case law under Article 34 TFEU, the Court has interpreted market access as a *process* rather than a specific moment.⁴² It has recognized that market access is not just achieved by allowing manufacturers to place their products on the market. Rules which have a negative impact on the use of products after they have been placed on the market can restrict market access and should, therefore, be within the scope of Article 34 TFEU. It is helpful to look at the reasons for why the Court extended the scope of Article 34 TFEU to restrictions on use. It appears that the Court adopted both a manufacturer- or business-centred perspective and a consumer-based perspective on market access. In *Mickelsson and Roos*, the Court made it clear that national rules that greatly restrict the use of a product effectively make it useless for manufacturers or importers to import that product.⁴³ After all,

41 ECJ 24 January 1991, C-339/89, *Alsthom Atlantique SA*, ECLI:EU:C:1991:28.

42 For a more detailed analysis of the concept of market access in free movement law, see J. SNELL, ‘The Notion of Market Access: A Concept or a Slogan?’, 47. *CML Rev* 2010, p 437.

43 C-142/05, *Mickelsson and Roos*, para. 26.

why would manufacturers or importers place a particular product on the market if the product could hardly be used at all? It is unlikely that there would be any demand for the product. This is closely linked to the expectations of consumers. Consumers will not be interested in buying a product if they know that they cannot use it.⁴⁴ As a result, the expectations of consumers play an important role in defining the scope of market access.

26. To conclude, the Court has adopted a significantly broader definition to market access under Article 34 TFEU than under the New Approach. The result is that the scope of the New Approach is relatively limited, whilst most national rules on use – including private law rules – can only be assessed under Article 34 TFEU. This has a negative impact on the effective application of the New Approach. A dynamic interpretation of market access will help to facilitate market access and increase the free movement of goods in the EU. Ultimately, the New Approach will be more successful as a regulatory strategy if its scope is extended beyond the initial market access stage. This includes the possibility of the New Approach having an impact on national private law rules.

4. Market Access and Private Law

4.1. A More Integrated Approach to Positive and Negative Integration

27. In the previous section, it was argued that the scope of the New Approach should be extended to cover national private law rules which have an impact on the use of products. In the next two sections, we will analyse precisely what impact the New Approach should have on private law to facilitate market access and to improve free movement of goods in the internal market. In other words, the focus will be on how much EU-law control of national private law rules on use is necessary for the effective application of the New Approach. We will have a closer look at the question to what extent the effectiveness of the New Approach requires changes to be made to national contract and tort law. Such an extension of the scope of the New Approach would inevitably have an impact on the interaction between positive and negative integration in the field of free movement of goods. The argument which has been developed above is that the Court should adopt a similar interpretation of market access under the New Approach to the interpretation which has been developed under Article 34 TFEU. Essentially, the interpretation of a concept used in negative integration would be used to extend the scope of application of positive integration – i.e. the harmonized standards under the New Approach. For both regulatory strategies, the Court would apply a dynamic interpretation of the concept of market access.

44 *Ibid.*, at para. 27.

28. On first sight, applying a concept developed under Article 34 TFEU to the New Approach in order to reduce the scope of application of Article 34 TFEU might seem paradoxical. However, it makes sense if one takes into account that the New Approach and Article 34 TFEU serve the same purpose – they both seek to improve the internal market for goods. Since both strategies play a complementary role, it does not matter if the scope of the New Approach is extended with the result that the scope of Article 34 TFEU is restricted. If this is a more effective way of guaranteeing free movement of goods, such an approach would be justified on the basis of the common aim to improve the internal market. If the application of the Irish Sale of Goods and Supply of Services Act 1980 was assessed under Article 34 TFEU, it would be possible that the Court found a restriction on free movement if the Irish legislation was held to restrict market access of foreign products. Such a restriction could still be justified by the Irish State by relying on the express derogations in Article 36 TFEU, or by relying on one of the mandatory requirements developed by the Court. The Irish State would also have to show that the restriction was suitable and necessary to achieve its aim. If the conclusion was that the Irish rules could not be justified, Ireland would have to remove the obstacle to free movement. EU law would not directly dictate what kind of rules should be adopted to replace the rules that breached Article 34 TFEU. This is precisely why it is argued that the scope of the New Approach should be extended to cover private law rules.

29. Under the New Approach, the EU has developed its own set of product standards that goods have to comply with before they can be placed on the market. These standards are by their very nature precise and specific. They set out in detail what the precise technical requirements are that goods have to comply with before they are presumed fit for use.⁴⁵ As such, they are suitable to be applied in contractual disputes in which courts have to assess the fitness for purpose of a product. Furthermore, the standards developed under the New Approach constitute total harmonization.⁴⁶ Although it is possible for manufacturers to establish compliance with the essential requirements through other means than through complying with the European standard, the essential requirements are the only allowed standard – it is not possible for Member States to impose higher or additional standards on products under the New Approach. The effect of the total harmonization would be compromised if Member States were entitled to apply different standards in private law disputes. Therefore, the scope of application of the standards adopted under the New Approach should be extended to cover private law disputes. The result would be that the scope of application of the New Approach and Article 34 TFEU might overlap more regularly. The question of

⁴⁵ See H. SCHEPFL, *Constitution of Private Governance*, p 232.

⁴⁶ This is confirmed by Art. 6(1) of Directive 89/106, discussed above.

whether the New Approach's reach should be extended should always be determined by an assessment of what is the most effective way of guaranteeing market access in the internal market. Ultimately, a more flexible approach to positive and negative integration, combined with a dynamic concept of market access, will be more successful in improving the functioning of the internal market for goods.

30. Two further reasons will be provided for extending the scope of the New Approach. First, the New Approach will be more effective as a regulatory approach to facilitate market access if it has an impact on private law rules. In *James Elliott* and *Schmitt*, the Court did not address the question of whether the effectiveness of the New Approach required that a link be made between market access and private law rules. In *Schmitt*, the opportunity was provided through the criteria laid down in *Paul*. However, the Court did not apply the second condition laid down in that case – does the *effet utile* of the directive require that individuals can claim damages if the directive has been breached?⁴⁷ In *James Elliott*, the questions of the Irish High Court did not explicitly address the effectiveness of the New Approach.⁴⁸ However, it would not have been difficult to make this link. It provides a degree of certainty to manufacturers to know that the European standards with which they have to comply to place their products on the market are also the standards that are used to assess whether the products are fit for purpose when they are actually being used. The artificial distinction between placing goods on the market and the use of goods does not make sense from the perspective of businesses, because there is a risk that they might be asked to comply with divergent standards in private law. Moreover, consumers will be able to know what standards a product should comply with under a contract for the sale of goods. This is likely to have a positive effect on consumer confidence and on the willingness of consumers to buy a product.

31. Second, and more fundamentally, extending the impact of the New Approach to private law rules would be consistent with the way in which the EU has 'operationalized' private law as a tool to shape and improve the functioning of the internal market.⁴⁹ In the last decades, the EU has increasingly harmonized aspects of private law by relying on Article 114 TFEU. The very precise contractual rules in the telecom and energy sectors provide good examples. More generally, the EU has adopted extensive consumer protection rules, which have a direct impact on private law. Many of these rules have been interpreted by the Court as total harmonization.⁵⁰ Therefore, Member States are not allowed to adopt divergent

47 C-222/02, *Peter Paul and others* (n 21), paras 42–47.

48 C-613/14, *James Elliott* (n 1), para. 31.

49 See H. MICKLITZ, 'The Visible Hand of European Regulatory Private Law: The Transformation of European Private Law from Autonomy to Functionalism in Competition and Regulation', 28. *YEL* 2009, p 3.

50 See V. MAK, 'Full Harmonization in European Private Law; A Two-Track Concept', 20. *ERPL* 2012, p 213.

standards. The standards adopted under the New Approach also constitute total harmonization, but the scope of that harmonization is limited to the initial market access stage. Furthermore, as a result of the EU's increasing impact on private law, the distinction between public and private law in EU law has become less clear. This has led to what Hans Micklitz has called European regulatory private law – a corpus of EU rules that have a direct impact on private law relationships.⁵¹ This development has resulted in a process of fusion of public and private law. As a result, the argument that the scope of the New Approach should not extend beyond administrative law becomes less convincing. For the New Approach, this means that the European standards *should* also have an impact on private law. In the next sections, we will analyse precisely what impact would be required in cases like *James Elliott* and *Schmitt* – in other words, how the broader argument that the New Approach should be extended to private law cases works out in practice.

4.2. *The New Approach and Liability in Contract Law*

32. In *James Elliott*, the Court of Justice held that the European standard and Directive 89/106 did not regulate the method through which the conformity of the product with the contractual requirements imposed by national law would be established. The national court did not have to use the mechanisms in the European standard to decide whether the aggregate was fit for purpose and of merchantable quality.⁵² Moreover, the national court did not have to apply the presumption of fitness for use under Directive 89/106 in a contractual dispute in which it was alleged that the aggregate was not fit for purpose when it was used.⁵³ As a result, the private law consequences of the New Approach are not regulated by EU law and Member States remain free to apply their own national rules on presumptions and burden of proof.

33. If it is accepted that the New Approach should have an impact on private law, there are essentially two strategies that could be used to make the link from the New Approach to private law. The first strategy could be described as a maximalist strategy, while the second would be a minimalist strategy. The maximalist strategy would require that the European standard, which provides the standards with which a product had to comply to be presumed fit for use under the New Approach, is also applied as the contractual standard of care. As such, the question of fitness for purpose would be exclusively decided on the basis of the European standard. The entire assessment by the national court would have to be based on the European standard. This would include rules on establishing conformity and presumptions of

51 H. MICKLITZ, 28. *YEL* 2009.

52 C-613/14, *James Elliott* (n 1), para. 53.

53 *Ibid.*, at para. 62.

conformity.⁵⁴ The only required change in private law would be that the methods used to establish the conformity or non-conformity of the product with the European standard would have to be applied at the moment of the *use* of the product – not at the moment of the goods being placed on the market. This maximalist approach would significantly reduce the flexibility of national courts in contractual disputes. It would limit the possibility to take the individual circumstances of a case into account. This is precisely why courts are generally reluctant to give a decisive role to standards in private law disputes. Therefore, it could be more effective to impose a strong – but rebuttable – presumption that the European standard should be applied as the contractual standard of care. Private lawyers might react to this argument by saying that this is already happening in practice. National courts often rely on European standards in setting the contractual standard of care – precisely like the Irish High Court in *James Elliott*. However, the difference with the maximalist approach would be that the application of the standard would be required *as a matter of EU law*.⁵⁵ This would bring the case within the scope of application of EU law, and would make it possible for national courts to make a preliminary reference. Moreover, the strength of the presumption – i.e. how easy it would be to rebut it – would also be determined by EU law.

34. A second way of extending the reach of the New Approach to private law could be described as a minimalist strategy, because it would go significantly less far than the approach described above. With this strategy, if a national court voluntarily decides to rely on a European standard in establishing the fitness for purpose of a product in a private law dispute – which is what the Irish courts had decided to do in *James Elliott* – , it would have to apply the rules of the European standard in solving the case. In other words, EU law would not require that the European standard is used as the contractual standard of care. But if a national court decides to adopt the European standard for the purpose of establishing the fitness for purpose of a product, then it *has* to play by the rules of the European standard. The impact on national law would be less extensive, because national courts would still be entitled to apply different standards under national law. However, if a choice to adopt the European standard was made, then at least the buyer and seller know that the dispute would be decided in accordance with the rules of the European standard. No additional set of standards or rules could be applied. In *James Elliott*, the standards for fitness for purpose in the European standard would then have been used to establish whether the implied condition of fitness for purpose under the Irish Sale of Goods and Supply of Services Act 1980

54 These rules were found the harmonized standard EN 13242:2002.

55 Another way of looking at this could be to say that national courts were under a duty of consistent interpretation to interpret the requirements of the national legislation in line with the European standard. I am grateful to Mislav Mataija for this suggestion.

had been complied with.⁵⁶ The methods for establishing compliance would be those provided in the European standard, with the exception that the fitness for use would have to be tested at the moment when the product was being used – not at the moment when it was placed on the market.

35. From the perspective of market access and free movement of goods, this second strategy would be less far-reaching and could still lead to divergent standards being applied in private law. The maximalist approach would be more attractive from the purpose of guaranteeing compliance with uniform European standards. However, the second approach would already be a good start to begin to extend the scope of the New Approach to private law. If, in practice, national courts already often rely on European standards in contract law disputes, the maximalist approach would not be necessary to guarantee and to improve the functioning of the internal market.⁵⁷ With the minimalist approach, the voluntary application of European standards in contract law would at least be brought within the scope of application of EU law.

4.3. *The New Approach and Liability in Tort Law*

36. In *Schmitt*, the Court held that the Medical Devices Directive did not give individuals the right to claim damages from certification bodies which were operating under the New Approach. The conditions for the liability of certification bodies were regulated by national law. It has already been argued above that this conclusion was based on a minimalist reading of the Court's judgment in *Paul*. Although the Court was right to conclude that the Medical Devices Directive did not include any provisions that indicated that it should be possible to hold certification bodies liable under EU law, the more fundamental question of whether the effective application of the Directive required this was not addressed. If the Court had applied *Paul* more broadly, it would have had to assess whether the aims of facilitating market access and protecting the health of end-users require that end-users can hold certification bodies liable. This would have required the Court to analyse what the impact of the potential liability of certification bodies would have been on the confidence of consumers in buying the product, and also on the health of consumers, which was expressly identified as one of the aims of the Medical Devices Directive.⁵⁸ One of the main reasons why Ms Schmitt had brought a claim against TÜV, and not against the manufacturer PIP, was that the manufacturer had gone bankrupt and, therefore, did not provide a reasonable chance of getting

56 Point 6.3 of the harmonized standard EN 13242:2002.

57 For a more detailed discussion of the reliance on European standards by national courts in contractual disputes, see B. VAN LEEUWEN, *European Standardisation of Services*, pp 146–155, and H. SCHEPEL, *Constitution of Private Governance*.

58 Case 219/15, *Schmitt* (n 2), para. 52.

compensation. The negligence claim against TÜV was an alternative to a claim against the manufacturer.⁵⁹

37. Overall, the key question is whether the possibility of tort liability of certification bodies should be required as a matter of EU law. This requires a broader assessment of the existing liability rules under EU law. The Product Liability Directive makes it possible for consumers to claim damages from manufacturers for damage suffered as a result of defective products.⁶⁰ However, if the manufacturer does not provide a realistic possibility of getting compensation, for example because they have gone bankrupt, EU law does not provide any alternative means of redress. In such cases, claimants have to rely on national law. In *Schmitt*, the Court held that the Product Liability Directive does not prevent the possibility of additional fault-based types of liability under national law, but the Court did not analyse whether the Medical Devices Directive *required* the possibility of liability under national law.⁶¹ If we focus on the effectiveness of the New Approach, the question is whether the potential liability of certification bodies in tort would improve market access and the protection of the health of end-users. First of all, would EU law liability of certification bodies help to improve consumer confidence? Would consumers like Ms Schmitt be more confident in buying breast implants if they knew that they could hold the certification body liable if it had acted negligently in the conformity assessment procedure? The link between the role of certification bodies under the New Approach and consumer confidence might seem remote. At the same time, after the PIP scandal, the market for breast implants received a serious blow, and many women have become less confident in buying breast implants.⁶² Therefore, it could be argued that the potential liability of certification bodies would help to restore confidence of consumers in the quality of breast implants in the EU. As such, it would increase the use of breast implants in the internal market. The strength of this argument would also depend on whether the possibility of liability would actually make certification bodies do a better job – i.e. whether they would act more diligently because they could potentially be held liable under EU law.

38. Furthermore, there is a close link to the second aim of the Medical Devices Directive, which is to protect the health of end-users. Would it be necessary to protect the health of end-users to impose liability of certification bodies under EU law? Again, this would depend on the extent to which EU law liability would have a

59 The context of and background to the case is discussed in detail in B. VAN LEEUWEN, 5. *EJRR* 2014.

60 Directive 85/374 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

61 Case 219/15, *Schmitt* (n 2), para. 58. See N. REICH, ‘Product Liability and Beyond: An Exercise in “Cap-Filling”’, 24. *ERPL* 2016, p 619.

62 See J. DE BRUYNE & C. VANLEENHOVE, ‘The “Breast-Taking” Consequences of the Poly Implant Prothèse case’, 24. *ERPL* 2016, p 823.

deterrent effect. It could be argued that the Court's recognition that certification bodies act to protect end-users is already sufficient to establish a duty of care in tort in national law. It would then not be necessary to impose this kind of liability under EU law. Furthermore, after the PIP scandal, the EU has already adopted stricter rules on the supervision of certification.⁶³ The public supervision of certification bodies has been strengthened.⁶⁴ Moreover, the obligations of certification bodies have been extended – the conformity assessment procedure has become more onerous.⁶⁵ These changes have been introduced to protect the health of end-users. From that perspective, it could be argued that it is not necessary for EU law to also impose liability in tort on certification bodies. With the extension of their obligations and the recognition that certification bodies act to protect end-users the liability of certification bodies in tort could safely be left to national law.

39. Overall, the conclusion could be that the effectiveness of the New Approach does not require that EU law regulate the conditions under which certification bodies can be held liable for negligence in the conformity assessment procedure. However, this question has to be expressly addressed by the Court. In doing so, it should not just focus on the wording of directives adopted under the New Approach, but it should also assess the potential liability of certification bodies in the broader framework for liability established by EU law. It is only after such an assessment that a conclusion can be drawn as to whether the effectiveness of the New Approach requires that a link be made between the EU rules on market access and the liability of certification bodies in tort.

5. Conclusion

40. In general, the Court is not reluctant to rely on the *effet utile* of EU law to extend the scope of application of EU law. Nevertheless, in *James Elliott and Schmitt*, the Court refused to extend the application of the New Approach to private law disputes. This is a missed opportunity, because the New Approach will be more effective in improving the free movement of goods if its 'reach' is extended to private law. Moreover, it would lead to a more harmonious interpretation of the concept of market access under the New Approach and Article 34 TFEU. Therefore, the Court should be encouraged to explicitly address the question of what role private law should play in guaranteeing the effective application of the New Approach.

41. If the Court is not willing to deal with this question, the private law implications of the New Approach should be addressed directly by the EU legislature. Rules

63 Regulation 2017/745 on medical devices.

64 Annex VII of Regulation 2017/745.

65 Annex IX of Regulation 2017/745.

on the application of European standards in contractual disputes could be included in New Approach directives. Similarly, the directives could include express rules on the potential liability of certification bodies. In the end, this might be the most effective way of making a link between the New Approach and private law, which would lead to a more consistent interpretation of the concept of market access in the internal market for goods.